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United States General Accounting Office

Report to Congressional Requesters

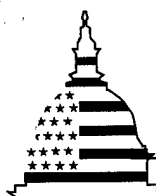
October 1999

GLOBAL HEALTH

Factors Contributing to Low Vaccination Rates in Developing Countries



19991021 053



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Contents

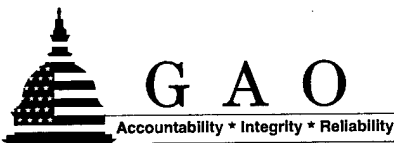
Letter	3
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Appendixes	Appendix I: Objectives, Scope, and Methodology	22
	Appendix II: Comments From the Centers for Disease Control and Prevention	24
	Appendix III: Comments From the U.S. Agency for International Development	26
	Appendix IV: GAO Contact and Staff Acknowledgments	31

Figures	Figure 1: Overall Immunization Coverage Rates for Countries, Grouped by Region, 1991-97	7
	Figure 2: Immunization Coverage Rates in the Poorest Countries, With and Without Conflict, 1991-97	9
	Figure 3: Immunization Coverage Rates for Measles and Tuberculosis in Sub-Saharan Africa, 1991-97	13
	Figure 4: UNICEF Expenditures on Immunization, 1990-98	19

Abbreviations

DPT	Diphtheria, pertussis, and tetanus vaccine
Hib	Haemophilus influenzae type b
PAHO	Pan American Health Organization
TB	Tuberculosis
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization



United States General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

B-283270

October 15, 1999

The Honorable Mitch McConnell
Chairman
The Honorable Patrick Leahy
Ranking Minority Member
Subcommittee on Foreign Operations
Committee on Appropriations
United States Senate

Over 11 million children under age 5 die each year in developing countries, and nearly three-quarters of these deaths result from infectious diseases. The World Health Organization estimates that the deaths of at least 4 million of these children are linked to their lack of access to vaccines. While long-term international initiatives have significantly increased global immunization rates, millions of children in the developing world, for various reasons, lack access to vaccines.

Recognizing the significance of children in the developing world not having access to vaccines, representatives from the international public health community, including the World Health Organization, the United Nations Children's Fund, the United Nations Development Program, the World Bank, the Rockefeller Foundation, and the Bill and Melinda Gates Children's Vaccine Program, along with the U.S. Agency for International Development and several other bilateral donors, have begun to explore options for improving immunization coverage in developing countries. They are seeking close collaboration with vaccine manufacturers and the governments of developing countries to devise strategies to meet current vaccine needs and to improve access to new vaccines as they are introduced.

In anticipation of the United States being asked to fund and provide other support for the renewed international effort to promote childhood immunization, you asked us to examine some of the key issues involving vaccine availability. As agreed with your offices, this report provides information and analyses on (1) the locations where shortfalls in immunization coverage are most prevalent and (2) the factors that impede vaccine availability in these locations. Our scope and methodology for this report are outlined in appendix I. We will report separately on our work

aimed at identifying the implications of various courses of action that Congress may want to pursue to increase vaccine availability.

Results in Brief

While global immunization coverage for six diseases¹ originally targeted by the World Health Organization has improved significantly since the mid-1970s, coverage rates are low for children living in the poorest countries, particularly in urban slums and remote rural areas. World Health Organization data indicate that the poorest countries of the world have vaccination rates that are about 26 percent below the global average of 82 percent.² In fact, immunization coverage in some countries in sub-Saharan Africa has declined over the last decade. Some countries in this region reported in 1997 that they immunized less than a third of their children against the six diseases targeted by the World Health Organization. Many of the children who are not immunized live in countries that have experienced internal conflict in recent years. Although the level of coverage varies, few children in developing countries have access to the newer vaccines that have been added more recently to the World Health Organization's list of recommended vaccines.

Several interrelated factors that poor countries have difficulty overcoming have limited the availability of vaccines for children in the developing world, including (1) inadequate health infrastructure, (2) the relatively higher cost of vaccines recently recommended by the World Health Organization, (3) insufficient information on disease burden³ and vaccine efficacy, and (4) changing priorities of international donors. In the 1990s, the U.N. Children's Fund and the U.S. Agency for International Development have begun to reduce their level of support for immunization.

¹Diphtheria, measles, pertussis, polio, tetanus, and tuberculosis.

²United Nations Children's Fund officials estimate that actual coverage rates are about 10 percent lower because of reporting errors by countries.

³Disease burden refers to the level of mortality and reduced quality of life associated with disease.

Background

The international public health community has played an important role in helping countries to improve immunization coverage. In 1974, the World Health Organization (WHO), which typically sets the global public health agenda, created the Expanded Program on Immunization to increase immunization of the world's children against six diseases—diphtheria, measles, pertussis, polio, tetanus, and tuberculosis. In 1980, the United Nations Children's Fund (UNICEF) established a goal of immunizing 80 percent of the world's children against these diseases by 1990 and called upon donors to contribute to this effort. The worldwide effort that was mobilized by the Expanded Program on Immunization helped countries increase immunization rates for these diseases from less than 5 percent of all children when it was established in 1974 to the current rate of 82 percent worldwide.⁴ In 1990, the international public health community created the Children's Vaccine Initiative as a forum for coordinating global efforts to further improve immunization and to promote research and introduction of new vaccines. More recently, WHO recommended that countries include several additional vaccines in their immunization schedules, namely hepatitis B, yellow fever for endemic countries, and *Haemophilus influenzae* type b (Hib).⁵

National governments are responsible for developing and managing their immunization programs, including sustaining vaccine delivery systems and determining which vaccines will be included in their immunization schedules. Immunization programs must compete with other important priorities such as education and nutrition. In the 1990s, donors and international organizations have encouraged developing countries to pay an increasing share of the cost of procuring vaccines. However, almost all developing countries still rely to some extent on the technical and financial assistance provided by international organizations and bilateral donor organizations like the U.S. Agency for International Development (USAID) to maintain their immunization programs.

⁴This is the average coverage for the vaccines used to prevent the six diseases originally targeted by WHO as reported by national governments to WHO in 1997.

⁵A vaccine against the Hib bacterium, which causes meningitis and pneumonia, was recommended by WHO for countries that have sufficient disease burden and infrastructure capability to warrant introduction.

Immunization Rates Are Lower Than the Global Average in Many Poor Countries

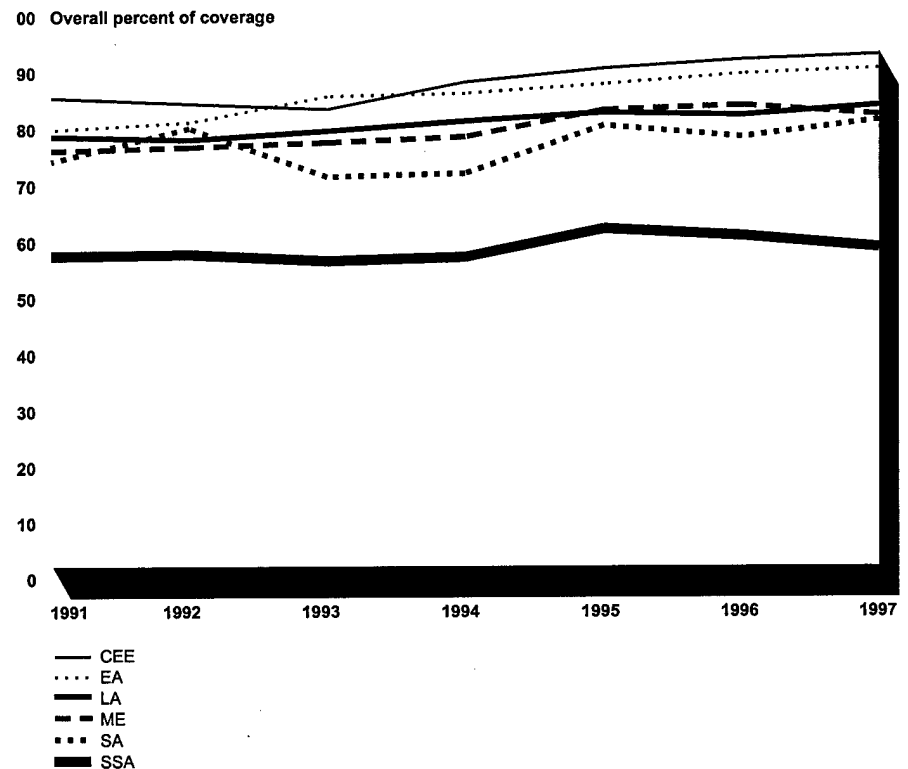
Immunization rates for the six WHO-targeted diseases in many of the poorest countries of the world are substantially lower than the global average of 82 percent. In some countries, coverage has declined in recent years. Moreover, few developing countries have included vaccines recently recommended by WHO for inclusion in national immunization programs.

Shortfalls in Coverage for Older Vaccines

Although five countries⁶ in other regions have coverage rates among the lowest in the world, most countries with immunization coverage below 60 percent are in sub-Saharan Africa (see fig. 1). In 1997, governments in this region reported immunizing only about 60 percent of their children against the original six targeted diseases. Chad, Sierra Leone, and the Democratic Republic of the Congo have the lowest rates in the region, providing vaccines to less than 31 percent of their children.

⁶ Afghanistan, Djibouti, the Lao People's Democratic Republic, Papua New Guinea, and Yemen.

Figure 1: Overall Immunization Coverage Rates for Countries, Grouped by Region, 1991-97



Legend:

CEE = Central and Eastern Europe
 EA = East Asia
 LA = Latin America
 ME = Middle East
 SA = South Asia
 SSA = Sub Saharan Africa

Note: Immunization coverage for diphtheria, measles, pertussis, tetanus, tuberculosis, and polio.

Source: GAO analysis based on data published by WHO in September 1998.

In addition, country studies conducted by donor organizations and national governments show that immunization coverage often varies markedly within countries, with substantially lower coverage rates in urban slums and remote rural areas. One USAID-funded survey, for example, found that in 1997, 65 percent of all children in Dhaka, Bangladesh, were immunized

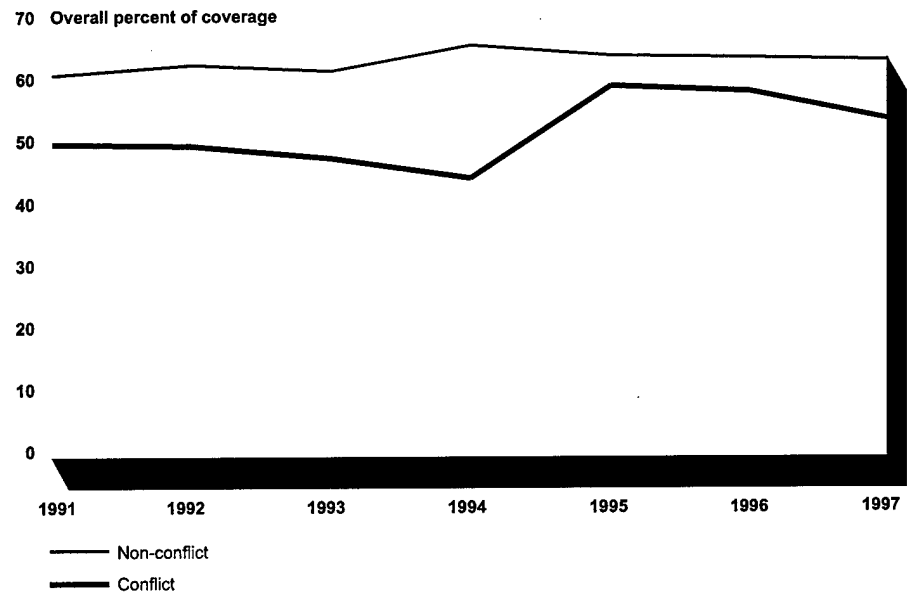
against measles, but only 46 percent of children in Dhaka's poorest neighborhoods had received the vaccine. Similarly, a 1998 study of measles coverage in Cambodia, prepared by the Cambodian Ministry of Health, showed that coverage rates ranged from over 75 percent in the capital region to below 30 percent in more remote regions. Other evidence includes a 1999 study by the Ugandan Ministry of Health that found that children in rural areas in Uganda were not immunized at all.

While the common characteristic of countries with low coverage is low per capita income and a corresponding low per capita spending on health,⁷ countries that have experienced civil conflict tend to have the lowest immunization rates. Of the 25 poorest countries in the world, 11 countries had recently experienced or were experiencing unrest.⁸ For the period 1991-1997, these 11 countries had immunization coverage levels that were on average about 19 percent below the countries with comparable per capita income that have not experienced conflict. (See fig. 2.)

⁷The World Bank estimates that the poorest countries of the world spend \$22 per capita on health each year, rising to \$209 for the wealthier developing countries.

⁸Afghanistan, Angola, Burundi, Cambodia, Chad, Ethiopia, Mozambique, Myanmar, Nigeria, Rwanda, and Sierra Leone.

Figure 2: Immunization Coverage Rates in the Poorest Countries, With and Without Conflict, 1991-97



Note: Immunization coverage for diphtheria, measles, pertussis, tetanus, tuberculosis, and polio.

Source: GAO analysis based on data published by WHO in September 1998 and on data compiled by Ruthann Leger Sivard, *World Military and Social Expenditures* (1998).

Coverage for New Vaccines Is Limited

Efforts by WHO to encourage countries to incorporate additional vaccines in national immunization programs—hepatitis B, yellow fever, and Hib—and to introduce tetanus coverage for pregnant women to protect babies at birth have not resulted in high coverage rates. In 1998, WHO reported in its summary of global vaccine coverage that few of the poorest developing countries had incorporated the hepatitis B vaccine⁹ into their immunization schedules despite the estimated 1 million deaths that this disease causes each year.¹⁰ Of the 48 countries that fit UNICEF's category of least developed (less than \$785 per capita income yearly), only 6 countries reported any coverage as of 1997.¹¹ In the six poor countries that have adopted the hepatitis B vaccine, immunization rates average only about 50 percent. Coverage rates for high-income countries that have adopted the vaccine average about 70 percent.

According to WHO, in 1997 only 12 of the 34 African countries at highest risk for yellow fever had included a yellow fever vaccine in their national immunization programs.¹² Only two countries in Africa—Côte d'Ivoire and the Gambia—reported coverage levels over 50 percent in 1997. Deaths associated with outbreaks in particular regions of countries can be significant. For example, in several remote mountain villages of Cameroon, WHO estimated that one epidemic in 1990 killed up to 1,000 villagers in 11 villages.

⁹In 1991, WHO recommended that all countries include the hepatitis B vaccine in their national immunization programs by 1997.

¹⁰Most of these deaths are among adults who were infected as children. Hepatitis B is the primary cause of liver cancer, which is the leading cause of cancer death in men in sub-Saharan Africa and much of Asia. It is also an important cause of cancer deaths in women.

¹¹Bhutan, Gambia, Kiribati, Maldives, Tuvalu, and Vanuatu.

¹²In 1988, WHO recommended that countries at risk for yellow fever outbreaks should adopt the vaccine into their national immunization programs. Yellow fever is endemic in 42 African and South American countries and several Caribbean islands.

WHO estimates that more than 277,000 children die each year from neonatal tetanus (tetanus developed within the first 4 weeks after birth). Because infants are infected by neonatal tetanus as a result of unclean delivery practices and equipment, without improvements in delivery conditions, the only way to protect newborns from the disease is to vaccinate expectant mothers. WHO reported in 1997 that 48 percent of pregnant women in developing countries do not pass on protective immunity to their babies against tetanus because they have not received the neonatal tetanus vaccine.¹³

WHO reports that 39 countries have added the Hib vaccine to their immunization schedules—primarily countries in the developed world. These 39 countries include only 12 percent of the world's children. However, a WHO official noted that 500,000 children die each year from this disease, mostly in developing countries. Some higher income developing countries have successfully introduced Hib into their immunization programs, particularly in South America and the Caribbean. As of December 1999, the Pan American Health Organization (PAHO) reported that 75 percent of all newborns in the region¹⁴ lived in countries that had adopted the Hib vaccine. However, in sub-Saharan Africa, where the risk of Hib is considered high by experts, only one country, the Gambia, has introduced the Hib vaccine.

Several Factors Impede Vaccine Availability in Developing Countries

Four principal factors have limited vaccine availability in developing countries: (1) inadequate health infrastructure, (2) the relatively higher cost of vaccines recommended recently by WHO, (3) insufficient information on disease burden and vaccine efficacy, and (4) changing priorities of international donors. The extent to which these factors impede vaccine availability varies by country, although some patterns exist across countries.

¹³Tetanus immunization is part of the three-dose diphtheria, pertussis, and tetanus (DPT3) vaccine that WHO recommended as part of the original six vaccines. To decrease deaths due to tetanus that occurred soon after birth, in 1989 WHO recommended the tetanus toxoid vaccine for pregnant women.

¹⁴There are 46 countries/territories in PAHO, spanning Canada, Central America and the Caribbean, South America, and the United States.

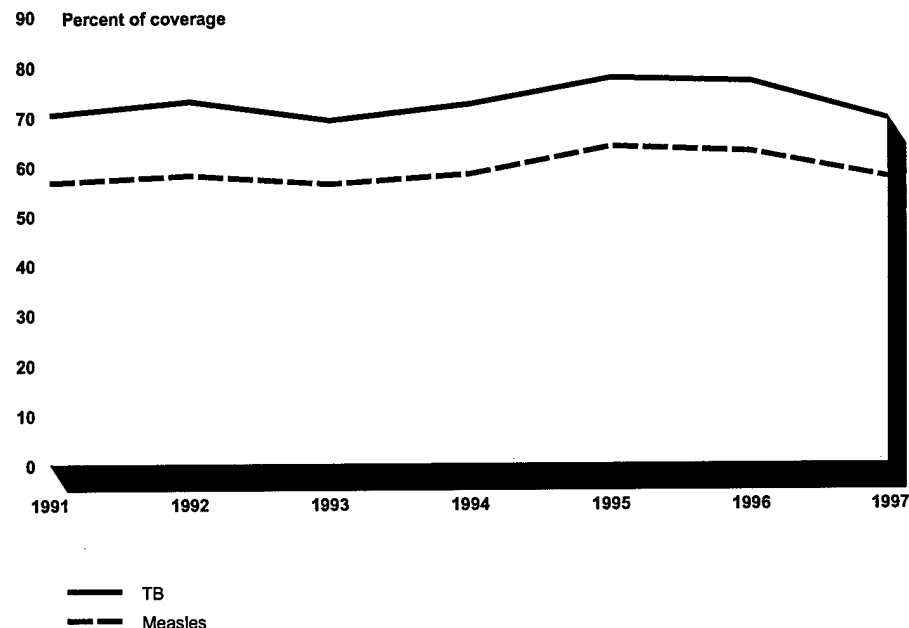
Inadequate Infrastructure Impedes Immunization Efforts

Countries must have systems that can safely and effectively deliver vaccines. WHO uses several indirect measures to assess countries' capability to implement vaccine immunization programs. These measures, which include countries' ability to administer vaccines at several intervals during the first year of life, to avoid vaccine waste, and to ensure vaccine quality, show that many developing countries have weak infrastructure. Inadequate infrastructure is most apparent in the poorest countries, resulting in low coverage rates, even when vaccines are donated. Typical problems include outdated or insufficient vaccine refrigeration and a lack of delivery trucks and trained health workers.

One indicator WHO uses to determine the ability of countries to effectively deliver vaccines is the percentage of children who have received the third dose of the combination vaccine for diphtheria, pertussis, and tetanus. Because three doses are required, this measure provides an indication of a country's capability to immunize children at several intervals during the first year of life. The results of this indicator show that the poorest countries, particularly in sub-Saharan Africa, are not sustaining the delivery of all three doses. For example, in 1997 Chad had coverage for the third dose of the combined DPT3 vaccine of 24 percent, while overall coverage for the six original vaccines was 31 percent. WHO believes the data reflect weaknesses in health delivery capabilities.

A second indicator of a country's capability to deliver vaccines is the percentage of children vaccinated against tuberculosis (TB) at birth and the percentage of all children receiving the measles vaccine at about 9 months of age. While some difference occurs in most countries, a greater difference indicates a less effective delivery system because it is often easier to reach a child at birth to administer a vaccine than at 9 months of age. On average, the percentage of children immunized against measles was about 10 percent lower than the immunization rate for tuberculosis. The poorest countries had the largest difference in coverage rates for tuberculosis and measles, with sub-Saharan African countries reporting a 12 to 15 percent difference in immunization rates for tuberculosis and measles (see fig. 3).

Figure 3: Immunization Coverage Rates for Measles and Tuberculosis in Sub-Saharan Africa, 1991-97



Source: GAO analysis based on data published by WHO in September 1998.

Another indicator of the status of a country's health infrastructure is the amount of vaccine that is purchased but not administered to children. The difference is considered waste by WHO and is used to indicate governments' ability to accurately estimate demand and to effectively deliver the vaccines. In 1997, WHO officials estimated that, on average, 43 percent of vaccines delivered to developing countries were not administered to children. Some of the loss occurs because many vaccines are heat sensitive and are left unrefrigerated for too long, resulting in a decrease in potency, so they must be discarded. In addition, vaccines have a limited shelf-life and must be disposed of if not used within that period. Finally, health care providers may decide to open a multidose vial to vaccinate one child even though the other doses are wasted, so as not to miss the opportunity to vaccinate the child. WHO estimates that much of the unused vaccine in developing countries resulted from poor planning regarding the amount of vaccine needed and the procurement of vaccine in large, multidose vials (10 to 20 doses). While multidose vials are the least expensive way to purchase vaccines, such factors as poor forecasting of

vaccine needs at delivery sites and inadequate training of health workers regarding the ability to use leftover vaccines led to unnecessarily high rates of vaccine waste. For example, in 1998, the difference between vaccines procured and vaccines used in Bangladesh ranged from 61 percent for DPT to 29 percent for measles. WHO has made efforts to reduce the amount of vaccine wasted by encouraging the use of a vaccine vial monitor that tracks time and temperature exposure of the polio vaccine to estimate its potency, and the procurement of vaccines in smaller vials. A WHO official told us that in order to avoid waste, countries are urged to use smaller vials for the more expensive hepatitis B and Hib vaccines. UNICEF reports that by the year 2000 it will require monitors on all heat-sensitive vaccines in an effort to increase confidence in vaccine potency and reduce waste.

Case studies of particular countries illustrate the problems that occur due to inadequate infrastructure. A 1998 special report by the United Nations Children's Fund on the immunization programs of eight countries in sub-Saharan Africa¹⁵ found that poor organization and management in vaccine distribution, maintenance of refrigeration, and immunization scheduling had resulted in an inefficient program. The study also found a shortage of properly trained staff. As a result, immunization coverage ranged between 30 and 35 percent in three of these countries—Chad, Mali, and Niger. Studies of Zambia and Bangladesh also pointed out excessive vaccine waste due to poor vaccine management practices. Health workers in both countries often did not know how to check DPT vaccine to ensure that it had not frozen (and consequently reduced its potency). A 1999 study prepared by the Uganda Ministry of Health found that health workers were inadequately trained to manage the immunization services and that these services were provided on an irregular basis due to the lack of transport.

Higher Prices for Newer Vaccines Limit Their Availability

Another factor inhibiting the availability of newer vaccines in developing countries is their relatively high price. While the price of vaccines declines over time as more suppliers enter the market, it has generally taken a decade after vaccines were first licensed before developing countries have begun to purchase them. Even as the prices have declined, they remain high relative to the cost of the older vaccines, and the poorest countries

¹⁵Vaccine Independence Initiative Implementation in 1997 and 1998, UNICEF (New York: Oct. 1998) Countries covered were Burkina Faso, Cape Verde, the Gambia, Mali, Mauritania, Niger, Senegal, and Chad.

have not included them in their immunization schedules. Moreover, donors have not generally funded purchases of the newer vaccines.

Vaccine companies cite the cost of research and development of vaccines as the primary reason for the higher prices of newer vaccines. According to vaccine company officials, the cost of developing a new product and bringing it to market is substantial, costing between \$100 million and \$300 million to license a vaccine in the United States. Royalty costs—the amount vaccine companies must pay to use production technologies that are patented by others, such as biotechnology companies—can also be high for new vaccines. In the case of hepatitis B, for example, WHO estimates that royalty costs are 13 to 15 percent of the sales price.

Experience with the introduction of hepatitis B and Hib shows that price was a factor inhibiting procurement by developing countries for almost a decade after the vaccines were first licensed and then they were only purchased by some higher income developing countries. For example, hepatitis B was introduced in the United States in the early 1980s at over \$30 per dose, with only two manufacturers supplying the vaccine. UNICEF and PAHO did not begin to purchase the vaccine until 1993 and 1994,¹⁶ respectively, after several competitive products had been introduced to the market and prices had dropped to less than a dollar per dose.¹⁷ The first Hib vaccines that were effective on infants were licensed in the United States in late 1987 and sold for about \$14 per dose. PAHO did not purchase this vaccine until 1998, when it was able to negotiate a price of \$2.18 per dose. However, very few of the poorest countries have purchased Hib or hepatitis B vaccines. According to WHO officials, price continues to be an impediment in these countries, in part because donors have generally not funded the purchase of these vaccines.

Insufficient Information Impedes Investment in Vaccines and Immunization Programs

Governments and donors need accurate information that can serve as a basis for deciding how much to invest in immunization programs. Surveillance data are crucial in assessing the impact of individual diseases, determining whether existing disease reduction targets are being met, and deciding where resources should be targeted for maximum impact. In

¹⁶UNICEF only purchased the vaccine for countries that reimbursed the agency. PAHO purchases the vaccines with money in its revolving fund but requires countries to pay for the vaccines.

¹⁷This is the price negotiated by PAHO for hepatitis B vaccine in 1998.

addition, information is necessary for citizens to help generate demand for vaccines. Even in developed countries that have sophisticated diagnostic equipment, disease burden data can be difficult to obtain. In much of the developing world, however, relevant data are inaccurate, inadequate, or are simply not collected. For example, Bolivia had refrained from making additional investments in its immunization system because government officials had accepted reports from the immunization program office claiming that immunization coverage was about 80 percent. Bolivian officials changed their position when a World Bank/PAHO team presented survey data indicating that the immunization coverage was closer to 40 percent.

Moreover, in 1996 WHO reported that a 28-country study uncovered wide-ranging problems in data gathering on disease prevalence. Many of the data that were collected were irrelevant, and health officials in developing countries did not have the necessary skills to analyze the data that were obtained. Disease burden data are very difficult to obtain because records indicating cause of death and illness are often inaccurate or incomplete. Without the use of sophisticated diagnostic methods, it is hard for health workers to determine the cause of death, particularly when malnutrition and other contributing factors are present.¹⁸ For example, WHO officials estimate that the incidence of yellow fever is up to 500 times greater than reported because of difficulty in diagnosing the disease and insufficiency of local health facilities in endemic countries.

Clinical vaccine trials are used to determine the efficacy of vaccines in particular countries and groups of countries. In wealthier countries where markets are assured for successful products, vaccine companies fund trials that are required for licensing. In developing countries, donor countries and multilateral organizations have had a more important role in funding clinical and disease burden studies. However, there has been limited clinical testing of vaccines in developing countries, and when they have been conducted, they were begun several years after vaccines were licensed in the developed world. For example, the first clinical tests for the Hib vaccine effective in infants were initiated by vaccine companies in the United States in 1984 and Finland in 1985, resulting in a U.S. license in 1987. It was 8 years after clinical trials began in the United States before trials

¹⁸UNICEF reported that malnutrition alone accounts for just 3 percent of deaths for children under age 5, but it plays a contributing role in more than half of all child deaths in developing countries.

began in a developing country. Clinical trials supported by donor countries and vaccine companies began in Chile in 1992 and a year later in the Gambia. In 1998, a Hib disease burden study, supported by USAID and WHO, was initiated in Indonesia. As a result of the time lag before clinical trials were conducted in poorer countries, governments in developing countries have not had information regarding the efficacy of new vaccines until several years after licensing in the developed world.

According to a WHO official, the choice of a site to conduct clinical tests on a new vaccine is typically determined by the existence of an infrastructure capable of sustaining a large trial. The challenge, according to the WHO official, is that in some cases the highest risk populations live in areas where the infrastructure is insufficient to support these trials. While smaller scale demonstration and pilot studies could be conducted to determine disease burden and vaccine efficacy in countries where infrastructure is weak, generally these have also not been conducted until several years after licensing in developed countries.

Information on disease burden and vaccine efficacy is critical for governments that must make vaccine investment decisions. For example, a vaccine that is expected to be licensed soon, pneumococcal conjugate, could be more effective in lessening the overall burden of pneumonia than the existing Hib vaccine. While the Hib vaccine immunizes against 20 percent of the disease strains that cause pneumonia, candidate pneumococcal conjugate vaccines may prevent up to 70 percent of the disease strains that cause pneumonia. Information from clinical trials could provide a better understanding of the burden of this disease in developing countries and the effectiveness of various vaccines so that governments have the information they need to make decisions regarding the purchase of additional vaccines.

These data limitations have prevented experts from conducting cost-effectiveness studies that could assist governments in determining the value of investing in additional vaccines. The Children's Vaccine Initiative, for example, found that of 190 published vaccination cost-effectiveness studies they identified, only about 10 percent pertained to developing countries—and most of those were of poor quality. The Children's Vaccine Initiative has recently developed analytical models to estimate the cost-effectiveness of introducing several additional vaccines into the immunization programs of developing countries, including hepatitis B and Hib.

Shifting Priorities of International Donors

In the 1970s and 1980s, after WHO created the Expanded Program on Immunization, the international donor community provided significant support to efforts to improve the availability of vaccines in developing countries. However, during the 1990s, overall commitments by bilateral donors for efforts to control infectious diseases, including immunization, have fluctuated significantly each year. The U.S. bilateral commitment through USAID declined slightly as a percentage of funding in the category of "child survival"¹⁹ over the 1990s. UNICEF spending for immunization decreased in dollar value and as a percentage of total health expenditures over the period. Within the pool of funds committed to control of infectious diseases, the global effort to eradicate polio received priority attention.²⁰ According to USAID and UNICEF officials, this has resulted in less money being available to support routine immunization programs.

The priority placed by bilateral donors on infectious diseases, which includes support for routine immunization and polio eradication as well as control of other diseases such as malaria and diarrheal diseases, shifted yearly throughout the 1990s. Annual spending commitments fluctuated by at least 39 percent per year and up to 330 percent. On average, however, infectious disease commitments slightly increased from 10.5 to 11.4 percent of total health commitments from the early to the later 1990s. An increasing percentage of infectious disease commitments was directed to support polio eradication, which increased from about 14 percent of infectious disease funding in 1995 to about 52 percent in 1997.

While USAID funding for overall child survival programs rose by more than 50 percent since 1990,²¹ from about \$223 million to about \$341 million in 1998, support for immunization programs declined as a percentage of funding for child survival programs. On average, immunization funding declined from about \$53 million (19 percent of child survival funding) between 1990 and 1993 to about \$51 million (17 percent of child survival funding) from 1994 to 1997. In 1998, immunization was only about \$47 million or 14 percent of the total obligated for child survival. Since

¹⁹These are programs designed to deal directly with the special health needs of children and mothers, including those aimed at improving immunization, nutrition, and sanitation.

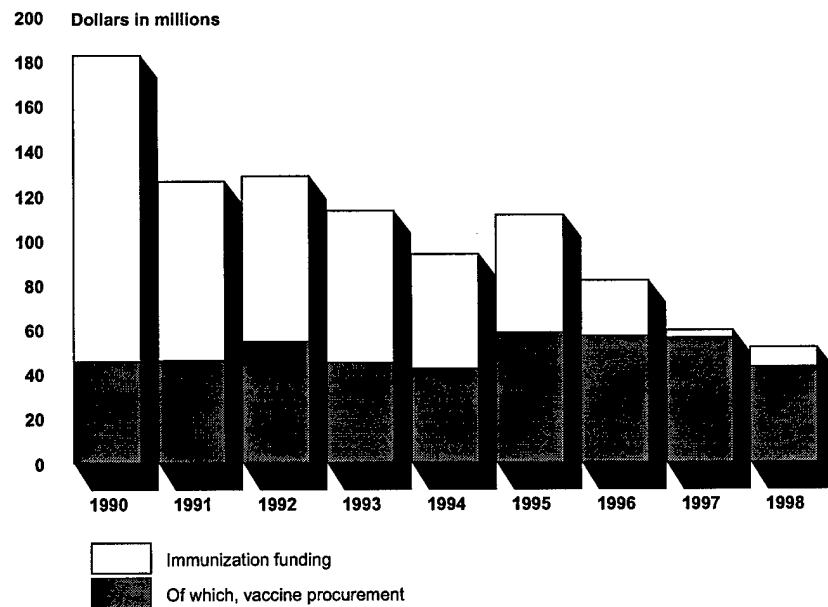
²⁰Polio eradication is an effort targeted specifically at ensuring that the incidence of polio is reduced to zero, thus obviating the need for further control measures.

²¹All USAID figures are fiscal year obligations.

polio eradication began in 1996, on average, about half of USAID's spending for immunization was directed toward this effort.

While UNICEF expenditures for health programs declined slightly from the early to the later 1990s, UNICEF funding for immunization declined more significantly both in terms of dollar value and also as a percentage of overall UNICEF expenditures (see fig. 4 for an illustration of UNICEF spending). Immunization funding decreased from about \$182 million (57 percent of health expenditures) in 1990 to about \$51.5 million (25 percent of health expenditures) in 1998. In addition, a growing percentage of immunization funds was spent on vaccine procurement, particularly to support the polio eradication effort, with vaccine procurement increasing from 25 percent of the total in 1990 to 83 percent of the total in 1998. As a result, support for other immunization services, such as maintaining national vaccine delivery systems, has declined.

Figure 4: UNICEF Expenditures on Immunization, 1990-98



Note: Expenditures are in constant 1997 dollars (in millions). UNICEF officials note that recent data coding changes may slightly increase the spending totals for 1997 and 1998.

Source: GAO analysis based on 1999 UNICEF data.

Almost no donor funding has been available to purchase more recently recommended vaccines. UNICEF, citing a lack of resources, has not purchased vaccine to prevent Hib for any country and only purchases hepatitis B vaccine on a very limited basis—for countries that reimburse UNICEF.²² A senior UNICEF official noted that the agency issued a formal policy in 1998 encouraging their country-level offices to take a leading role in introducing Hib and hepatitis B in their countries. However, these offices did not receive additional funds and have chosen not to use their existing funds to purchase the newer vaccines. PAHO has a revolving fund that procures hepatitis B and Hib vaccines but is reimbursed by countries that place the orders. These countries benefit from the lower prices that can be negotiated with larger procurements by UNICEF and PAHO and are allowed to reimburse the agencies with local currency, rather than in dollars, which must be used to purchase the vaccines. In addition, the Asian Development Bank is considering providing financial support for purchasing hepatitis B and Hib for its borrowing member countries.

Agency Comments

The Centers for Disease Control and Prevention and USAID provided written comments on a draft of this report that are reprinted in appendixes II and III. The Centers for Disease Control and Prevention stated that it generally agrees with the overall message, noting that the report provides an excellent introduction to the status of vaccination in developing countries and the barriers that exist to expanding coverage and implementing new vaccines. The Centers stated that one of the most valuable observations made in the report was that developing countries were facing different barriers in their attempt to increase vaccination rates. However, the Centers noted that we did not mention an important barrier—the lack of advocacy for vaccination from the medical community and the public. We regard advocacy as a potential option to address immunization shortfalls rather than a barrier and therefore we did not discuss this matter in the report. The Centers also provided technical comments that we incorporated as appropriate.

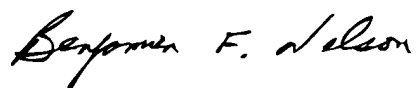
USAID stated that the report presented the issue clearly, concisely, and fairly. USAID noted the importance of making investments in immunization programs within the context of broader health and developmental priorities and emphasized the need for USAID and national governments to

²²The European Union Initiative, which purchases vaccines for several countries in western Africa, does not provide support for the purchase of more recently recommended vaccines.

balance health investments to address all priorities. While agreeing with our observation that overall coverage rates in African immunization programs were low, USAID pointed out that some countries in Africa have developed strong national programs that indicate the potential for program improvement in other countries in the region. USAID also noted that vaccine costs are a small percentage of the total cost associated with immunization programs and that its implementation strategy assumes a certain amount of waste. All of USAID's points are valid, but they do not affect our primary message. Thus, we did not modify the report.

As agreed with your offices, unless you publicly announce the contents earlier, we plan no further distribution of this report until 3 days after its issue date. At that time, we will send copies of this report to appropriate congressional committees; the Honorable Madeleine K. Albright, Secretary of State; the Honorable Donna Shalala, Secretary of Health and Human Services; the Honorable J. Brady Anderson, Administrator of USAID; and other interested parties. We will also make copies available to others on request.

Please contact me on (202) 512-4128 if you or your staff have any questions concerning this report. Other GAO contacts and staff acknowledgments are listed in appendix IV.



Benjamin F. Nelson, Director
International Relations and Trade Issues

Objectives, Scope, and Methodology

At the joint request of the Chairman and the Ranking Minority Member of the Senate Committee on Appropriations, Subcommittee on Foreign Operations, we identified the (1) locations where shortfalls in immunization coverage are most prevalent and (2) factors that impede vaccine availability in these locations.

To identify locations of shortfalls in immunization coverage, we reviewed pertinent documents and analyzed data collected from the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), and the World Bank for the years 1991 to 1997. UNICEF and WHO collect information on immunization coverage from each country for the six originally targeted diseases (that is, diphtheria, measles, pertussis, polio, tetanus, and tuberculosis). WHO also collects coverage information on hepatitis B, *Haemophilus influenzae* type b (Hib), neonatal tetanus, and yellow fever. While some experts maintain that immunization coverage rates provided by country officials are overstated, WHO and UNICEF conduct country-specific surveys to verify accuracy and make adjustments where necessary. We used reported immunization coverage from WHO to calculate the global coverage rate for the six original vaccines for 1997, the most recent year for which data are available. Data for 1998 will be available in September 1999, but WHO officials said that they did not expect any significant changes in the trends we identified.

We examined patterns of immunization across regions of the world and by selected countries. To obtain a better understanding of the immunization shortfalls that we identified, we reviewed reports on the immunization programs of specific countries. We used national economic data from the World Bank to identify the relationship between immunization rates and per capita income. We also reviewed the 1998 report, *World Military and Social Expenditures*, on the existence of conflict and civil unrest in developing countries to identify their correlation with immunization coverage. Finally, we attended two international vaccine conferences in Geneva, Switzerland, and New York to interview and collect information from national immunization program officials about the factors that impeded immunization coverage for older vaccines and the adoption of new vaccines in their programs.

We primarily relied on reports and unpublished papers from WHO and UNICEF to describe the burden of disease for vaccines that have been recommended by WHO for inclusion in national immunization programs. As much of the disease burden information for developing countries is lacking, WHO develops models to estimate disease burden. We spoke with

officials from the five global vaccine manufacturers and the National Institutes of Health to ascertain the status of candidate vaccines in the research pipeline. We relied on a WHO report on the anticipated licensing of new vaccines for data on the expected mortality from diseases that would be prevented through the widespread availability of these vaccines.

To examine the factors that impede vaccine availability in the developing world, we interviewed officials from multilateral organizations, pertinent federal agencies, vaccine manufacturers, key foundations, and vaccine experts in academia. We also collected and reviewed documents such as WHO and UNICEF annual reports on immunization coverage, special publications on vaccines, and professional papers obtained from these sources. We interviewed officials responsible for vaccine issues at the Pan American Health Organization (PAHO), WHO, the World Bank, UNICEF, and the United Nations Development Program. We also interviewed pertinent program officials at the Centers for Disease Control and Prevention, the Commerce Department, the Food and Drug Administration, the National Institutes of Health, the State Department, and the U.S. Agency for International Development (USAID). We interviewed representatives of the Rockefeller and Gates Foundations and the vaccine divisions of Chiron; Merck & Co. Inc.; Pasteur Merieux Connaught; SmithKline Beecham; and Wyeth Vaccines and Nutrition. Finally, we interviewed a number of academic experts in the vaccine field who have been particularly active at the international level. We questioned these officials about their perceptions of the barriers that have impeded greater availability and use of vaccines by developing countries.

In addition, we collected and reviewed relevant reports, journal articles, and other publications that discussed key impediments to vaccine availability. Finally, we obtained vaccine price data from the Centers for Disease Control and Prevention, PAHO, and UNICEF. We interviewed officials at these organizations and vaccine companies to obtain insights into why prices changed over time. We did not independently verify the statistical data that were obtained from various sources.

We performed our review from July 1998 through August 1999 in accordance with generally accepted government auditing standards.

Comments From the Centers for Disease Control and Prevention



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

SEP 23 1999

Benjamin F. Nelson, Director
International Relations and Trade Issues
U. S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Nelson:

Thank you for the opportunity to review the GAO draft report, "Global Health: Factors Contributing to Low Vaccination Rates in Developing Countries" (NSIAD-00-04). The CDC generally agrees with the overall report, which provides an excellent introduction to the status of vaccination in developing countries and the barriers that exist to expanding coverage and implementing new vaccines. Below are some comments for your consideration.

General Comments

The major conclusion of the section on "Shifting Priorities of International Donors" can be more explicitly stated in the first paragraph of that section. The major conclusion is that funding for immunization programs has been reduced as USAID and UNICEF have shifted a larger portion of their available health funding away from immunization programs, in spite of substantial increases in the child survival budgets. This suggests that support of immunization programs has been markedly reduced in priority relative to other child survival programs. For example, apparently the USAID immunization funding decreased from 24% of child survival funds in 1990/1993 (53/223) to only 14% of available funds in 1998 (47/341). Similarly, UNICEF immunization funding, as a percentage of its health programs, decreased from 57% of health expenditures in 1990 to 25% in 1998. While polio eradication activities may have resulted in less funds available to support routine immunization programs to a limited extent, the primary issue is that, during this decade, health funds have been shifted away from immunization programs.

One of the most valuable observations made by the report is the difference in the barriers that certain developing countries face. Barriers that are most important in one region may not necessarily be key in others. For example, while cost is the primary barrier to introducing Hib vaccination in Sub-Saharan Africa, the lack of knowledge concerning disease burden is probably much more important in many Asian countries. When cost is not the primary barrier in countries, the shifting priorities of international donors also becomes less relevant in those specific countries. Thus, in interpreting the information presented in this report, and in developing strategies that will overcome barriers, one must not just look globally but by specific country.

Appendix II
Comments From the Centers for Disease
Control and Prevention

Page 2 - Benjamin F. Nelson

An important barrier not highlighted in the report is the importance of advocacy for vaccination from the medical community and the public. A lack of advocacy makes it easy for policy makers to decide to fund programs other than vaccination. In contrast, when there is a demand for vaccine, funding may be found. For example, implementation of Hib vaccination in Chile occurred, in part, because of concern about meningitis in children. And in Fiji, donated Hib vaccine was used for several years; then following the end of the donation, the government decided to purchase the vaccine which had become part of the routine schedule. It is very important to highlight the need for support (from providers and the public) of vaccination in general and of new vaccines in particular, because even with sufficient funding, infrastructure, and disease burden information, vaccination is unlikely to occur in the absence of demand.

Technical Comments

Page 2, paragraph 2, line 6, "... explore options for improving immunization coverage in developing countries.": At the beginning of September, the formation of the Global Alliance for Vaccines and Immunization (GAVI) was announced, which intends to do just that.

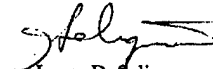
Page 5, Capitalized heading, "Immunization Rates are Lower Than the Global Average in Certain Countries": Suggest replacing it with the following heading: "Immunization Rates in Poorest Countries Are Substantially Below Global Average"

Page 6, section entitled "Shortfalls in Coverage . . .," and in the figures: It would be beneficial to include the US and developed economies as a point of reference for comparison to the other regions.

Page 11, paragraph 1, last sentence: Since UNICEF manages the contracts with the vaccine manufacturers that supply the vaccines and vial monitors, GAO may want to consider obtaining comments from appropriate UNICEF officials on the availability of vial monitors for all vaccines by the year 2000.

Please contact Carolyn Russell, Director, Management Analysis and Services Office, (404) 630-0440, if you have questions concerning these comments.

Sincerely,


James D. Seligman
Acting Director, Office of
Program Support

cc:
NIP, Martin Landry
NCID, Sarah Wiley

Comments From the U.S. Agency for International Development



U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

SEP 30 1999

Mr. Henry L. Hinton, Jr.
Assistant Comptroller General
National Security and
International Affairs Division
U.S. General Accounting Office
441 G Street, N.W. - Room 4039
Washington, D.C. 20548

Dear Mr. Hinton:

I am pleased to provide the U.S. Agency for International Development's (USAID) formal response on the draft GAO report entitled "Global Health: Factors Contributing to Low Vaccination Rates in Developing Countries" (October 1999).

We would like to congratulate the GAO staff that prepared the report. They have presented a very complex issue clearly, concisely and fairly. We are delighted to see the bipartisan Congressional interest in the performance of national immunization programs in the developing world and their potential for improving health, reducing poverty, and accelerating development. For over twenty years, USAID has considered support for these programs an important element of its developmental portfolio. I look forward to reviewing the recommendations that result from the upcoming panel discussions.

National immunization programs are currently preventing between 3 and 4 million deaths per year in the developing world. Improved utilization of existing vaccines could prevent an additional 2 to 3 million deaths. However, investments in immunization programs by both USAID and local governments must be made within the context of broader health and developmental priorities. USAID establishes health priorities based on criteria, one of which is disease burden (see figure enclosed). This has resulted in USAID making investments in activities that address malaria, HIV/AIDS, diarrhea, acute respiratory infections, tuberculosis, malnutrition, and basic systems for service delivery. USAID and national governments must

1300 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20521

**Appendix III
Comments From the U.S. Agency for
International Development**

2

continually balance investments to effectively address all these priorities. USAID encourages countries to assume more responsibility and take ownership for their own national immunization programs.

We believe it is important to note that while the overall coverage rates for the third dose of DTP (DTP3) are generally low for African immunization programs and very low for most of the countries in the Sahel, there are African countries that have developed very strong national immunization programs that continue to perform very well in tough economic times. South Africa, Botswana, Malawi, Swaziland, Zambia and Zimbabwe all have programs that report coverage close to or over 70 percent for DTP3. There are also several countries in West Africa with robust programs, most notably Cote d'Ivoire, which is now paying for all of its own vaccines. This indicates that with strong national political commitment and trained personnel, immunization programs in Africa can be substantially improved.

Although vaccine wastage was identified as an issue in the report, it is also important to note that the cost of vaccine represents a small portion of the total cost of delivering an immunization. Studies by the REACH project indicate that the cost of the standard six antigens is usually about 6 percent of the total cost of immunization during the first year of life. Vaccine wastage is excessive in many programs and can be reduced through improved management. However, some wastage will always occur because the priority of national programs is to fully vaccinate the infant population in a timely fashion. The program must minimize the number of missed opportunities for providing an immunization. If only one infant shows up for a session and needs to be vaccinated for measles, a multi-dose vial will be opened, the infant vaccinated and the balance of the vaccine discarded for safety reasons. We support this strategy.

Finally, as stated in the report, the price per dose of vaccines is the lowest when vaccine is ordered in multi-dose vials. Based on the prices quoted to the Pan American Health Organization for 1999 procurements, it is cheaper to waste 8 doses of measles vaccine (from a 10 dose vial) than to buy two doses of vaccine in single dose vials.

USAID is concerned about the dwindling resources dedicated to immunization programs and their declining performance. We are taking several steps to address these problems. Most recently we have worked with our partners, principally WHO and UNICEF, to

review the status of immunization programs, and conducted reviews of the impact of health sector reforms and financial support at the national level in many countries. This information, coupled with an analysis of immunization program performance over the past six years in Africa, will form the basis for targeting future investments and improving the impact of current investments. We currently support independent collection of data and analysis of the performance of health programs including immunization (e.g., the recent collection of coverage data that resulted in the revamping of the Bolivian immunization program was support in part by USAID/Bolivia). In Africa, we have identified target countries where we will be working very closely with WHO/AFRO and UNICEF to shore up the existing infrastructure and improve national performance. Additional countries will be added to that list as we explore new strategies that allow the national programs to routinely deliver immunizations to even the most difficult-to-reach populations. A variety of strategies will be explored to address the specific capabilities and limitations of each country.

USAID is providing significant support to the global effort to eradicate polio. We have provided about 51 percent of donor funding support for the effort in the Latin America and the Caribbean since 1986. When feasible, the Agency is using the opportunity of the polio eradication effort to support the development of the health systems necessary to achieve eradication as well as the provision of routine services, including other vaccines.

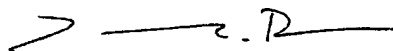
USAID recognizes the tremendous potential new vaccines hold for improving child survival. Since 1996, USAID has also worked extensively with the Children's Vaccine Initiative, to develop comprehensive agendas and workplans for use by all the partners to accelerate the introduction of new vaccines. These plans have formed the basis for the investments of many of our partners including the Bill and Melinda Gates Children's Vaccine Program. Some constraints to the inclusion of new antigens are the limited resources available to national governments for the procurement of the vaccine, the provision of an adequate cold chain, and trained personnel. USAID has recently completed an analysis that will provide governments the information they need to determine the financial mechanisms that may be most useful in their setting. This should improve the ability of governments to increase the resources available to support their own immunization programs.

Appendix III
Comments From the U.S. Agency for
International Development

4

Thank you for the opportunity to respond to the GAO draft report and for the courtesies extended by your staff in the conduct of this review.

Sincerely,

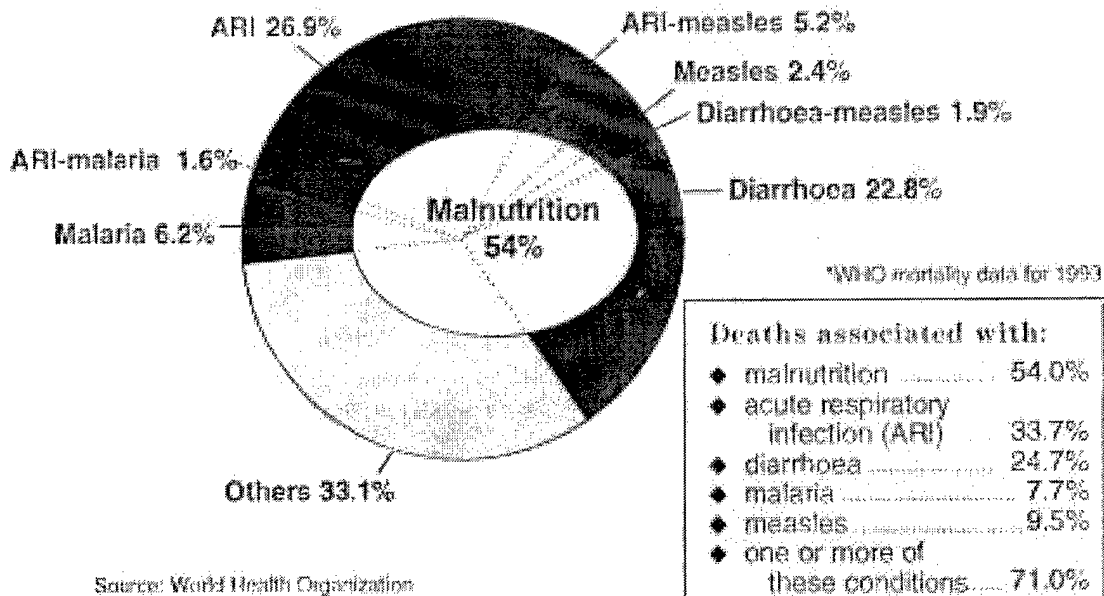
A handwritten signature in dark ink, appearing to read "T. J. Brown", with a stylized flourish at the end.

Terrence J. Brown
Assistant Administrator
Bureau for Management

Enclosure: WHO Mortality Data



Distribution of 12.2 Million Deaths* Among Children Less Than 5 Years Old in Developing Countries Worldwide



GAO Contact and Staff Acknowledgments

GAO Contact

Lynne Holloway, (202) 512-4612

Acknowledgments

In addition to Ms. Holloway, Claude Adrien, Maria Durant, Bruce Kutnick, Thomas Laetz, Mike McAtee, Rona Mendelsohn, and Raymond Wyrsh made key contributions to this report.

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